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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/511,776	02/24/2000	Roger K Craig	4256/86197	5653

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EXAMINER

GABEL, GAILENE

ART UNIT	PAPER NUMBER
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1641

DATE MAILED: 02/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action	Application No. 09/511,776	Applicant(s) CRAIG ET AL.	
	Examiner Gailene R. Gabel	Art Unit 1641	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 26 January 2004 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

- a) ☒ The period for reply expires 5 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.
ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☐ The proposed amendment(s) will not be entered because:
- (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);
 - (b) ☐ they raise the issue of new matter (see Note below);
 - (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
 - (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____.

3. ☒ Applicant's reply has overcome the following rejection(s): 35 USC 112, second paragraph rejection.
4. ☒ Newly proposed or amended claim(s) 1,2,4-8 and 10-14 would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: 1,2,4-8 and 10-14.

Claim(s) objected to: NONE.

Claim(s) rejected: 19 and 20.

Claim(s) withdrawn from consideration: 15-18.

8. ☐ The drawing correction filed on _____ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____.
10. ☐ Other: _____

Continuation of 5. does NOT place the application in condition for allowance because: claims 19 and 20 does not obviate the teaching of the prior art of record.

ADVISORY ACTION

Amendment Entry

1. Applicant's amendment and response filed 1/26/04 is acknowledged and has been entered. Claims 21 and 22 have been cancelled. Claims 15-18 remain withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention. Currently, claims 1, 2, 4-8, and 10-20 are pending. Claims 1, 2, 4-8, 10-14, and 19-20 are under examination.

Rejections Withdrawn

2. In light of Applicant's argument, the rejection of claims 1, 4-8, 10-14, and 19-20 under 35 U.S.C. 112, second paragraph, is hereby, withdrawn.
3. The double patenting rejection of claims 1, 4-8, 10-14 and 19-20 under 35 U.S.C. 101 as claiming the same invention as that of claims 1-13 and 18-21 of copending Application No. 09/258,452, is withdrawn, in light of Applicant's abandonment of ASN 09/258,452.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 19-20 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Prusiner et al. (US 5,891,641) in view of Foster et al. (US 4,444,879) for reason of record.

Response to Arguments

5. Applicant's arguments filed 1/26/04 have been fully considered but they are not persuasive.

A) Applicant argues that the combination of Prusiner et al. with Foster et al. do not suggest the kit of the claimed invention. Applicant specifically argues that Prusiner et al. do not teach a first labeled binding partner which binds to the protein in a manner dependent on the conformational state of the protein and a second labeled binding partner that is independent of the conformational state of the protein and generates a signal in a manner dependent on the binding of the first binding partner to the protein. Applicant argues that the recitation of "sandwich format" does not infer that the second

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antibody is labeled. According to Applicant, Foster et al. do not remedy the deficiency of Prusiner et al.; therefore, the combination of Prusiner et al. with Foster et al. does not render the claimed invention, obvious.

In response, the recited antibodies in claims 19 and 20 read on the teaching of Prusiner et al. of labeled antibodies, which bind to the protein dependent and/or independent of the conformational state of the protein and which may be used in a sandwich format of an assay (see column 16, lines 25-38). To reiterate, Prusiner et al. disclose a method for determining a diseased related conformational state of a protein such as PrP^{Sc} in a sample by contacting the protein with a *labeled antibody that binds (has a higher binding affinity) to the protein in a manner dependent on the conformational state of the protein; i.e. PrP^C (native or non-disease state) or PrP^{Sc} (diseased conformation)* in column 4, lines 24-56, column 12, lines 4-28, an column 17, lines 49-58). The antibody is detectably labeled with fluorophores, radioisotopes, enzymes, etc. so as to detect labeling of the protein wherein a generation of signal is indicative of the conformational state of the protein (see column 12, lines 64-67). Prusiner et al. also disclose contacting the protein with a second antibody in a sandwich format (see column 16, lines 25-38). Antibody binding to the disease related conformation is measured using time resolved, dissociation enhanced fluorescence (see column 17, lines 62-65). Additionally, sandwich formats do not exclude use of a labeled capture antibody. See Bonte et al. (Clinical Chemistry and Laboratory Medicine, 2/1999) and Bronstein et al. (US Patent 5,800,999) literature, both of which teach labeled capture antibody in a sandwich format.

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A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art, i.e. labeled first and/or second antibody. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

6. Claims 1,2,4-8 and 10-14 are allowed.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gailene R. Gabel whose telephone number is (703) 305-0807. The examiner can normally be reached on Monday, Tuesday, and Thursday, 5:30 AM to 2:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (703) 305-3399. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-0169.

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Gailene R. Gabel

Patent Examiner

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August 21, 2003

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Christopher L. Chin

CHRISTOPHER L. CHIN

PRIMARY EXAMINER

GROUP ~~1800~~ 1641